UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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iRhythm Technologies, Inc.
Petitioner,

v.

Welch Allyn, Inc.
Patent Owner

IPR2025-00363 (Patent 10,159,422)
IPR2025-00374 (Patent 8,965,492)
IPR2025-00376 (Patent 9,155,484)
IPR2025-00377 (Patent 8,214,007)
IPR2025-00378 (Patent 8,214,007)

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I. INTRODUCTION

The Acting Director's denial of iRhythm's five IPR petitions has unsettled the IP community.[1] Those denials rest solely on a discretionary denial consideration first announced after iRhythm filed its petitions: the "settled expectations of the parties, such as the length of time the claims have been in force." The Acting Director concluded that, because iRhythm cited a parent application to the challenged patents in an IDS years ago, "settled expectations favor denial of institution" for all five IPRs. The Decision should be vacated for three reasons.

First, the Decision fails to consider the complete set of settled expectations between the parties. Among other facts not considered, iRhythm, an American innovator spun out of Stanford University, launched its first life-saving cardiac monitor in 2012—the same year the earliest challenged patent issued. iRhythm then continued to innovate, releasing additional products in 2017 and 2021. Yet until its 2024 lawsuit, Welch Allyn let its patents lie dormant. It never commercialized nor

[1] *E.g.,* Hackman, et. al., *Discretionary Denial Rulings May Spur Calls for PTAB Reform*, LAW360 (June 27, 2025); Dani Kass, *Unsettling Expectations: Stewart Broadens Denials Again*, LAW360 (June 20, 2025); Dani Kass, *Stewart's Newest Discretionary Denial Has Attys On Edge*, LAW360 (June 10, 2025); Dani Kass, *Patent Office Leader Rejects IPRs Based On 12-Year Wait*, LAW360 (June 6, 2025).

asserted them and now seeks simply to tax the commercial market it watched iRhythm build through millions of dollars of investment. The Decision does not consider the expectations Welch Allyn's inaction created, including leading iRhythm (and the entire market) to believe that Welch Allyn would not assert its patents, and therefore that iRhythm (and others) had no reason to challenge them.

Second, the Acting Director has stated laudable goals of reducing the PTAB's workload and improving patent quality. The Decision, however, runs contrary to both. It incentivizes mass filing of IPRs, even for patents that may never be asserted, a wasteful outcome for both parties and the PTAB. By citing iRhythm's IDS submission as evidence of "awareness" of the entire patent family, it discourages patent applicants from conducting prior-art searches. That, in turn, increases the burden on examiners to find the most relevant prior art, reducing examination efficiency and quality. And by immunizing older patents from the scrutiny of highly qualified APJs, the Decision allows low-quality patents to linger until litigation targets invalidate them in district court—the very burden Congress designed the AIA to relieve.

Third, by creating the concept of "settled expectations" after iRhythm filed its petitions and applying the rule retroactively, the Director violated the Administrative Procedure Act and iRhythm's Due Process rights. The rule also violates the Director's own binding precedent in *NHK*, which held that discretionary denial is

not appropriate due merely to the age of the challenged patent when petitioner received no "tactical advantage" from its alleged delay in filing a petition.

The Acting Director should vacate the institution denials and order the Board to consider iRhythm's petitions on the merits. That outcome is warranted given the parties' expectations here, the implications of the new rule, and the lack of a legal basis to apply "settled expectations" to the iRhythm IPRs at all, much less in a way that contradicts the Director's own binding precedent.

II. FACTUAL BACKGROUND

A. iRhythm Invents and Patents a New Wearable Cardiac Monitor and Receives FDA Approval in 2012.

iRhythm was formed in 2006 to solve a critical medical problem: the underdiagnosis of cardiac arrhythmias, a serious condition that can lead to stroke, heart failure, and even death. At the time, the available outpatient cardiac monitors required multiple wires connected to several adhesive electrodes placed on a patient's chest, as well as a recording device, often worn on a belt or shoulder strap. These bulky, complicated devices provided poor-quality data and limited patient compliance because they could not be worn during normal activities, like bathing.

After spinning iRhythm out of a Stanford program and six more years of outside-investment-funded research, iRhythm's founders revolutionized the cardiac monitoring field by launching a lightweight, wearable cardiac monitor that allowed

patients to enjoy normal daily activities and provided high quality ECG data. To safeguard its investments, iRhythm sought patent protection for its innovations.

In 2012, the FDA approved the first commercial embodiment of iRhythm's patents, the Zio® XT patch. Zio® XT was the first wearable cardiac monitor to offer up to fourteen days of uninterrupted monitoring. By combining this class-leading lifespan with a comfortable and unobtrusive design, the Zio® XT dramatically increased patient compliance and allowed for higher arrythmia detection rates and a faster time to diagnosis compared to existing solutions.

iRhythm continued to invest and develop new products. It released its Zio® AT product in 2017, which allows for near real-time transmission of patient data to clinicians. And in 2021, the FDA approved the Zio® Next-Generation, a smaller and lighter product, which improved wearability to increase patient compliance. Over eight million patients have worn iRhythm's life-saving Zio® devices.

iRhythm's success is a testament to the power of innovation and the critical support provided by the U.S. patent system. Patents fueled iRhythm's ability to raise funds from investors, invest in research and development at its U.S. facilities, and bring groundbreaking technology to U.S. patients. Its journey exemplifies how the patent system, when used as intended, fuels innovation, protects investment, and delivers real-world impact.

B. Welch Allyn Does Nothing With its Patents for Twelve Years.

The four challenged patents claim priority to the same application filed in November 2006. Their alleged novelty stems from specifying certain components of a wearable cardiac monitor as reusable or disposable, and from the incorporation of resistors into electrical traces. As the Petitions explain, these features were well-known, obvious, and did not advance the field. It was common and routine to make disposable those cardiac monitor components that adhere to a patient's skin (e.g., for sanitary reasons) and to make reusable expensive components, such as printed circuit boards. -363 Petition at 3-5. Similarly, regulators, such as the FDA, recommend cardiac monitors incorporate resistors to survive defibrillation, and controlling resistance through electrical traces had been done for decades. -377 Petition at 5-7.

Between 2012 and February 2024, Welch Allyn let the '007 patent family lie dormant. The oldest challenged patent, the '007, issued in July 2012, the same year that FDA approved the Zio® XT. The '492 and '484 patents issued in 2015, and the '422 patent followed in 2018. Despite having these patents at the ready, and iRhythm's release of new Zio® products in 2017 and 2021, Welch Allyn never asserted that iRhythm infringed its patents until launching a lawsuit in February 2024. Nor has Welch Allyn ever claimed to have made a product embodying *any* claim of the challenged patents. *See* Compl., *Welch Allyn, Inc. v. iRhythm, Inc.*, No.

1:24-cv-00224-MN, Dkt. 1 (D. Del. Feb. 20, 2024).[2] In short, Welch Allyn allowed iRhythm to invest and build the market and now seeks to use its patents only to extract a royalty after iRhythm's customers came to trust and appreciate its designs.

C. After iRhythm Files its IPRs, the Acting Director Adopts New Discretionary Denial Rules.

iRhythm timely filed its IPR petitions. Its December 2024 filing met the AIA's requirement that a petition be filed within one year of service of a patent-infringement complaint. 35 U.S.C. § 315(b). iRhythm's petitions also aligned with the timing considerations from two Board decisions then-Director Iancu designated precedential: *NHK Spring Co. v. Intri-Plex Techs., Inc.*, No. IPR2018-00752, 2018 WL 4373643 (P.T.A.B. Sept. 12, 2018) and *Apple Inc. v. Fintiv, Inc.*, No. IPR2020-00019, 2020 WL 2126495 (P.T.A.B. Mar. 20, 2020). *NHK* explains that a petition will not be discretionarily denied even when a petitioner knew about the challenged patent for over a decade, so long as the petitioner received no "tactical advantage" from the alleged delay. 2018 WL 4373643, at *7. And *Fintiv* describes various factors considering the status of co-pending litigation. 2020 WL 2126495, at *2.

On March 26, 2025, the Acting Director issued interim guidelines that announced new considerations for discretionary denial, including the concept of

[2] Welch Allyn's parent, Hillrom, does not list any of the challenged patents on its patent marking page. https://www.hillrom.com/en/about-us/patents/.

"settled expectations." *See* Memorandum on Interim Processes for PTAB Workload Management (March 26, 2025) ("March 26 memo"). Beyond its one line, the March 26 memo did not explain how the factor works in practice, give examples of relevant facts regarding such "expectations," or reference precedent. *Id.*

D. The Acting Director Denies iRhythm's Petitions Based Solely on "Settled Expectations."

On June 6, 2026, the Acting Director discretionarily denied iRhythm's petitions. She noted that "[s]everal arguments weigh against discretionary denial" including various *Fintiv* considerations, such as the timing of the district court litigation and likelihood of a stay, and she also rejected Welch Allyn's argument that iRhythm overly relied upon expert testimony. Decision at 2-3. Yet she declined to have the Board assess the merits because iRhythm had filed an IDS citing the application that issued as the '007 patent. *Id.* at 3. The Acting Director contended that, in light of the IDS submission, "settled expectations favor denial of institution," and "outweigh[] the above-discussed considerations." *Id.*

The Acting Director claims to have considered the totality of the evidence and argument. *Id.* at 2. But her decision fails to consider: (i) that the FDA approved the Zio ® XT the same year the '007 patent issued, but Welch Allyn delayed twelve years to assert its patent; (ii) the lack of evidence that Welch Allyn knew iRhythm was purportedly aware of its patents before it filed suit, or that Welch Allyn relied on any action by iRhythm to assume iRhythm would not challenge its patents; (iii) that,

under *NHK*, an alleged delay in filing a petition does not warrant discretionary denial absent evidence that the petitioner received a tactical advantage; (iv) that the March 26 memo was the first time any authority suggested that the age of a patent was relevant to the availability of IPR review; and (v) that a citation to a pending patent application in an IDS alone is insufficient as a matter of law to show knowledge of the patent that issued from that application, much less later-issued family members.

III. ARGUMENT

A. The Acting Director Failed to Consider All Expectations.

Welch Allyn's decision to let its patent lie dormant for a dozen years undermines any settled expectation that its patents would not be subject to IPRs. As the Acting Director recently recognized, where a patent has "been in force for years but [has not] been commercialized, asserted, marked, licensed, or otherwise applied in a petitioner's particular technology space," those facts "weigh against a patent owner's claim of settled expectations." *Intel Corp. v. Proxense LLC*, IPR2025-00327, Paper 12 at 2-3 (P.T.A.B. June 26, 2025). *All* of those facts are present here.

The Decision never accounted for Welch Allyn's choice to lie in wait as iRhythm launched the Zio® XT and continued to release additional products over the next twelve years. This is not a situation where Welch Allyn was filing suits against other competitors in the industry such that it was only a matter of time before Welch Allyn came after iRhythm. Nor is it one where the patent owner

commercialized and marked its product. It is one where a patent owner let its patents lay dormant for over a decade, as entire industries sprung up around it.

What's more, Welch Allyn could have had no reasonable expectation that the age of its patents immunized them from *inter partes* review. When Congress wants to bar patents of a certain age from post-issuance challenges, it makes its intent express. It did just that in the American Inventors Protection Act of 1999, which introduced *inter partes* reexamination. Pub. L. No. 106–113, 113 Stat. 1501. There, Congress immunized "patents issued before 1999" from those challenges. H.R. Rep. No. 112-98, pt. 1, at 46–48 (2011). Congress also precluded post-grant review (PGR) of "old" patents by restricting those challenges to patents with post-AIA effective filing dates. *See* AIA §§ 3(n)(1), 6(f)(2)(A). Yet Congress took the opposite tack for *inter partes* review. It "eliminated" the *inter partes* reexamination carveout so that "all patents can be challenged in inter partes review." H.R. Rep. No. 112-98, at 46–48. Rather than restrict *inter partes* review challenges based on a patent's age or priority date, Congress required only that a petitioner wait for the nine-month PGR window to expire (if applicable), 35 U.S.C. § 311(c), and file within one year of being served with a patent-infringement complaint, 35 U.S.C. § 315(b). "Congress's choice to depart from the model of a closely related statute is a choice neither we nor the agency may disregard." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 364 (2018).

If Congress's express intent weren't enough, *NHK* is dispositive. Since 2019,

that Director-designated precedent has been "binding Board authority in subsequent matters involving similar facts or issues." PTAB Standard Operation Procedure 2 (Rev. 11), § II.D (2023). *NHK* states that even a ten-year delay in challenging a patent is not enough to preclude an otherwise timely challenge absent evidence that the petitioner received a "tactical advantage" from waiting to file its petition. 2018 WL 4373643, at *7. The record here lacks any suggestion that the timing of iRhythm's petitions provided it any tactical advantage. The only party receiving a tactical advantage here is Welch Allyn, as the decision rewards it for lying in wait as iRhythm invested millions to develop its products and bring them to patients.

Given the above, and that over 80% of patents involved in post-grant challenges are involved in co-pending litigation,[3] it strains credulity to believe that Welch Allyn would have expected its lawsuit to prompt no IPRs.

B. The New Rule Will Increase PTAB Workload, Undermine the Integrity of the Patent System, and Reduce Patent Quality.

In exercising its discretion to deny an IPR petition, the Director should consider "whether efficiency and integrity of the system are best served by denying or instituting review." *Fintiv*, 2020 WL 2126495, at *3 (citation omitted). In so doing, the Director seeks to "balance considerations such as … fairness[] and patent quality," *id.* at *2, consistent with "an objective of the AIA … to provide an effective

[3] An Analysis of Multiple Petitions in AIA Trials, at 10 (Oct. 24, 2017).

and efficient alternative to district court litigation," *NHK*, 2018 WL 4373643, at *7 (quoting omitted). The Director also accounts for the PTAB's "capacity to conduct AIA proceedings" and "promote consistent application of discretionary [denial] considerations in the institution of AIA proceedings." March 26 memo at 3.

The new rule resulting from the Acting Director's application of the "settled expectations" factor in the iRhythm IPRs advances none of those goals.

1. Requiring immediate IPR challenges will unnecessarily increase the PTAB's workload and stifle innovation.

The Acting Director interpreted "settled expectations" to preclude IPRs for patents of some (unidentified) age. The result is that potential challengers must file IPRs or PGRs against any marginally relevant patent as soon as possible—regardless of whether the patentee threatened or asserted the patent.

No one benefits from such a rule. As the sheer number of patents issued far exceeds the number ever asserted or threatened,[4] the new rule will increase IPR or PGR challenges—contrary to the Director's goal of reducing the PTAB's workload.

Indiscriminate challenges will also needlessly burden patent holders. Innovators seek patent protection to attract investors and protect their investment as

[4] *See* Mark A. Lemley, *The Surprising Resilience of the Patent System*, Tex. L. Rev. at 40 (Dec. 2016) (explaining that "[o]nly 1%-2% of patents are ever litigated, and only a few percent more are licensed for a royalty without ever being litigated").

they enter the market. But when assessing whether to file a patent application, innovators (and investors) will now need to consider the likelihood, if not certainty, that at least one petitioner will challenge their patents shortly after issuance. Defending such challenges is far more costly and expensive than obtaining a patent in the first place, forcing innovators to choose between spending their limited dollars to defend their patents or to bring a product to market. This will have an outsized effect on small businesses and startups seeking to commercialize new technologies.

Potential challengers face the same dilemma. They must now spend resources monitoring newly issued patents and immediately challenge them rather than focusing on their own innovations and products. For companies that sell complicated products that include hundreds or even thousands of components or features, the new rule imposes an impossible requirement to police all newly issued patents that are possibly relevant to any component of not only current, but also future, products.

Encouraging inconsequential disputes is antithetical to the AIA and bad policy. Congress sought "to establish a more efficient and streamlined patent system that will improve patent quality *and limit unnecessary and counterproductive litigation costs.*" H.R. Rep. No. 112-98, at 40 (emphasis added). The new rule does the opposite. It requires parties to litigate and the Board to decide validity for scores of patents that the market will ultimately determine lack commercial significance. Federal courts do not entertain disputes based on such "trivial risk[s] of harm."

Gubala v. Time Warner Cable, Inc., 846 F.3d 909, 911 (7th Cir. 2017) (Posner, J.). And, while a party need not have Article III standing to file an IPR, standing's purpose to keep the federal courts from being "flooded" by trivial lawsuits should inform the PTO's policy choices. *Id.*

2. The new rule deters patent applicants from searching for prior art, reducing patent quality.

The Director has also stated that discretionary denial seeks to improve "patent quality" and the "integrity" of the patent system. The new rule serves neither aim.

Congress recognized the importance of having as much relevant art in front of the examiner as possible. It wanted "to increase the opportunities for the examiner to have the best prior art available during examination," H.R. Rep. No. 110-314, at 37 (2007) (referencing what became 35 U.S.C. 122(e)), to "help the agency increase the efficiency of examination and the quality of patents." 157 Cong. Rec. S1097 (daily ed. Mar. 2, 2011) (statement of Sen. Hatch)).

By denying iRhythm's petitions because it cited one of Welch Allyn's patent applications in an IDS, the new rule undermines patent quality. Applicants will now fear that the Director will deny their petitions solely because they cited a patent application in the same family in an IDS. The new rule thus encourages applicants to refrain from conducting comprehensive prior art searches before filing. This will result in fewer references before the examiner, undermining examination efficiency and increasing the risk that examiners will allow low-quality claims.

C. The New Rule is Arbitrary and Inconsistent with Precedent.

The Acting Director's interpretation of the new rule violates numerous laws and the USPTO's own precedent. First, retroactively applying the new rule as the sole basis to deny iRhythm's already-filed petitions violates both the APA and Due Process. As to the APA, the PTO lacks authority to "promulgate retroactive rules." *Tafas v. Dudas*, 511 F. Supp. 2d 652, 666 (E.D. Va. 2007). And "general statements of policy" can only be applied prospectively. *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993); 5 U.S.C. § 552(a)(2)(D)(ii). For the same reasons, retroactive application runs afoul of iRhythm's Due Process rights. *See, e.g.*, *Kirwa v. U.S. Dep't of Def.*, 285 F. Supp. 3d 21, 41 (D.D.C. 2017).

Second, the APA requires agencies to inform parties of the matters of "law asserted." 5 U.S.C. § 554(b)(3). The March 26 memo fails this mandate. Other than stating it considers "the length of time the claims have been in force," it provides no guidance on the contours of the rule. And no reasonable reading of the rule would suggest that it would outweigh all other considerations previously used by the PTAB or that an IDS citing a patent application would mandate discretionary denial where the patent owner sat on its rights for over a decade.

Finally, leveraging the rule to reach a result plainly at odds with Director-designated precedent addressing near-identical facts compounds the problem. *See NHK*, 2018 WL 4373643, at *7. *NHK* ruled that an otherwise timely petition would

not be denied based on alleged delay unless there was a "tactical advantage, or opportunity for tactical advantage, that Petitioner gained by waiting to file the Petition." *Id.* Here, Welch Allyn has not alleged, and cannot allege, any tactical advantage iRhythm gained from timely filing its petitions only after Welch Allyn filed suit. *NHK* thus supports neither discretionary denial nor the result here. Indeed, that precedent mandates the opposite outcome.

IV. CONCLUSION

IPRs allow innovators, like iRhythm, to efficiently challenge invalid patents so they can continue to innovate, rather than expend resources fending off dubious patent lawsuits brought by those lying in wait to capitalize on other's commercial success. The rule resulting from the Acting Director's application of the "settled expectations" factor undermines these goals and the agency's own policy objectives. The Acting Director should take this opportunity to, at minimum, clarify that the "settled expectations of the *parties*" is not a one-way, myopic focus on the age of the claims or when the petitioner first "learned" of them. It must consider the patent owner's actions (or inaction) too. The analysis should also be in harmony with the precedent that has guided the Board for half a decade—not contrary to it. And the Acting Director should make clear that, in situations as here where no other factor supports discretionary denial and the "settled expectations of the parties" is equivocal at best, the factor does not warrant denial of meritorious petitions.

Dated: July 3, 2025

FENWICK & WEST LLP

/Robert E. Counihan/
ROBERT E. COUNIHAN
Reg. No. 61,381

Attorney for Petitioner
iRhythm Technologies, Inc.

CERTIFICATION OF SERVICE

The undersigned certifies that on July 3, 2025, I caused a true and correct copy of the foregoing iRHYTHM'S REQUEST FOR DIRECTOR REVIEW to be served electronically via email to the Director – PTAB Decision Review and to counsel of record for the Patent Owner at the following:

Director_PTABDecision_Review@uspto.gov

Eric J. Halverson
K&L Gates LLP
4 Embarcadero Center, Suite 1200
San Francisco CA 94111
erik.halverson@klgates.com

Anna Rebekah Hill
Jared R. Lund
K&L Gates LLP
70 W. Madison Street, Suite 3100
Chicago, IL 60602
rebehak.hill@klgates.com
jared.lund@klgates.com

Dated: July 3, 2025

FENWICK & WEST LLP

/Robert E. Counihan/
ROBERT E. COUNIHAN
Reg. No. 61,381

Attorney for Petitioner
iRhythm Technologies, Inc.